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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,921	02/17/2004	Frank L. Meyskens JR.	UCIVN-058C	1912

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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,921	MEYSKENS ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/17/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-99* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-40, 43-49, and 53-55, drawn to methods of decreasing spermine and/or spermidine levels in a human prostate cell by administering α-difluoromethylornithine (DFMO), classified in class 435, subclass 375.

II. Claims 41-42, 50-52, 56, and 71-83, drawn to methods of treating a subject having prostate cancer (including inhibiting the development, metastasis, or progression of said prostate cancer) by administering DFMO, classified in class 514, subclass 673.

III. Claims 57-70, drawn to methods of treating a subject having prostate cancer by administering DFMO further comprising a second therapy, classified in class 514, subclass 673.

IV. Claims 84-87, drawn to a method of treating benign prostate hyperplasia in a human by administering DFMO, classified in class 514, subclass 673.

V. Claims 88-95, drawn to a method of treating benign prostate hyperplasia in a human by administering DFMO and a second therapeutic agent, classified in class 514, subclass 673.

VI. Claims 96-99, drawn to a method of treating benign prostate hyperplasia in a human by administering DFMO together with saw palmetto extract, classified in class 514, subclass 673.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of Group I has a materially different function and effect than the methods of Groups II-VI. Group I is drawn to the *in vitro* reduction of spermine and/or spermidine in a human prostate cell whereas the methods of Groups II-VI are drawn to the *in vivo* treatment of human pathologies (namely prostate cancer and benign prostate hyperpasia). In addition, the inventions are mutually exclusive; the in vivo methods of Groups II-VI do not overlap the scope of and are not obvious variants of the *in vitro* method of Group I.

Inventions II and III are directed to related methods of treating prostate cancer. The related inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.*, are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method claims of Group III comprise administration of DMFO and a second therapeutic agent whereas the method of Group II only requires administration of DMFO. The two inventions do not overlap in scope, as the method of Group III requires a substantially different composition for the desired effect. In addition, the mode of operation of treating prostate cancer with DMFO in combination with a second

therapy as claimed in Group III would be materially different than that of Group II. To search both inventions would present an undue burden on the Examiner because the search for a treatment of prostate cancer using a composition comprising DMFO would not be the same search required for a treatment of prostate cancer using a combination of DMFO and a second therapy.

Inventions II-III and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups II-III and IV-VI are unrelated because the methods of Groups II-III are drawn to treating prostate cancer whereas the methods of Groups IV-VI are drawn to treating benign prostate hyperplasia (BPH). It is art recognized that there is little correlation between the two diseases. BPH refers to an increase in the size of the prostate leading to symptoms of urinary hesitancy, frequent urination, increased risk of urinary tract infections and urinary retention. Prostate cancer refers to a disease in which cancer develops in the prostate. The treatment of these two conditions is distinct. Prostate cancer is generally treated with anticancer drugs and/or radiation therapy whereas BPH is generally treated with alpha blockers and antiandrogen therapy. In addition, the search for treatment of BPH would not be the same as the search for treatments of prostate cancer. As such, searching the inventions of Groups II-III and Groups IV-VI together would present an undue search burden on the Examiner.

Inventions IV and V-VI are directed to related methods of treating BPH. The related inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.*, are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method claims of Groups V-VI comprise administration of DMFO and a second therapeutic agent whereas the method of Group IV only requires administration of DMFO. The two inventions do not overlap in scope, as the method of Groups V-VI requires a substantially different composition for the desired effect. In addition, the mode of operation of treating BPH with DMFO in combination with a second therapy as claimed in Groups V-VI would be materially different than that of Group IV. To search both inventions would present an undue burden on the Examiner because the search for a treatment of BPH using a composition comprising DMFO would not be the same search required for a treatment of BPH using a combination of DMFO and a second therapy.

Inventions V and VI are directed to related methods of treating BPH. The related inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.*, are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method claim of Group V comprises administration of DMFO and a

second therapeutic agent whereas the method of Group VI requires administration of DMFO in combination with saw palmetto extract. The two inventions do not overlap in scope, as the method of Groups V requires a substantially different composition for the desired effect. In addition, the mode of operation and mechanism of treating BPH with DMFO in combination with saw palmetto extract as claimed in Group VI would be materially different than that of Group V. In addition, to search both inventions would present an undue burden on the Examiner because the search for a treatment of BPH using a composition comprising DMFO and "a second therapy" (*e.g.* an antiandrogen) would not be the same search required for a treatment of BPH using a combination of DMFO and saw palmetto.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species Requirement

This application contains claims directed to the following patentably distinct species: the multitude of "second therapies" encompassed by Claim 57 of Group III. The species are independent or distinct because of the multitude of possible second therapies encompassed by the claim. To search for a treatment of prostate cancer by administering DMFO and a "second therapy" would present an undue search burden on the Examiner. Any and all methods of treating prostate cancer wherein DMFO is

present in the composition would satisfy the generic claim of "further comprising a second therapy" as recited in Claim 57.

If Applicant elects Group III for prosecution on the merits, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 57 is generic. Applicant is required to elect a single disclosed second therapy for prosecution on the merits (*e.g.* antioxidant, retinoid, prostatectomy, radiation). In addition, if the second therapy is a class of compounds, Applicant is further required to elect a single disclosed compound of that class for prosecution on the merits.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Joint Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Examiner
Art Unit 1614

May 22, 2006

Ardin H. Marschel 5/30/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER